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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,066	10/27/2004	W Wayne Lautt	14430.5USWO	8639

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,066	LAUTT, W WAYNE	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5,6,8-10,12-15,17-19,21-33,36 and 43-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-3, 5-6, 8-10, 12-15, 17-19, 21-33, 36 and 43-45* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/16/07;7/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/16/07 and 7/13/07 are acknowledged and has been reviewed.

Claims 2-3, 5-6, 8-10, 12-15, 17-19, 21-33, 36 and 43-45 are pending.

Claims 2, 5, 9, 14, 17-19, 22-28 are amended.

Claims 1, 4, 7, 11, 16, 20, 34-35 and 37- 42 are cancelled and claims 43-45 are newly added

Response to Arguments

The response filed **3/16/07**presents remarks and arguments to the office action mailed **11/17/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 12 is objected to because of the following informalities: line 2 after "at least one of" the wording insulin, insulin analog and sulfonylurea should be omitted because page 11 of the specification recites all the compounds described as "insulin, insulin analog and sulfonylurea agents". Appropriate correction is required.

Claim 12 is further objected to see line 9 the abbreviation SIN-1 should be spelled out when first used and the abbreviation in parenthesis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 5, 9-10, 12, 14-15, 17-19, 21, 25-29, 31-32, 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiele et al., Thiele et al., (1957) "Decrease in urinary sugar in diabetes mellitus by vagotonic treatment with neoeserine", *Munch Med Wochenschr.,* Aug 23;99(34): 1203-1206 (Applicants IDS) in view of American Diabetes Association 1998 as evident by drugdelivery.ca and http://syndromex.stanford.edu/InsulinResistance.htm.

Thiele et al. teach neoeserin lowers sugar level in urine as required by instant claims 2, 5, 9, 14 and 43-45. Neoeserin is known in the art as neostigmine and is similar to physostigmine as evidence by drug delivery.ca., wherein the patients is

human as required by instant claims 8 and 32 with diabetes. The reference further teaches neoeserin is a vagotonic functional alteration, (i.e., relating to as defined) therefore targets the liver as required by instant claims 10 and 21. See English translation lines 29-the end. The reference further teaches oral administration of neoeserin in a tablet form, see lines 5-9 English translation. One of ordinary skill in the art would have been motivated to physostigmine or neostigmine inplace of neoeserin because the reference teaches that these drugs are similar or the same and would expect success in doing so.

American Diabetes Association teaches administering troglitazone to insulin-treated patients with type II diabetes mellitus as required by instant claim 31. It is well known in the art that Insulin-resistance" is the hallmark of Type 2 Diabetes Mellitus as evidence by http://syndromex.stanford.edu/InsulinResistance.htm.

With regard to the various forms of administration in claims 25-29, one of ordinary skill in the art would know that medication route refers to the way that a drug is introduced into the body. The decision on the route is based upon the specific medication being used, the rate of absorption desired and the specific site of action. For example oral administration is slow intravenous, intraperitoneal is faster than oral, used when a more complete and faster absorption is desired. One of ordinary skill in the art would be motivated to use a more appropriate form of administration based on the desire end result. For example for high levels of glucose in the blood a physician would be

motivated to administer the drug intravenously for the medication to reach its target and work immediately to drop the level of glucose down.

The cited art failed to show combination as required by instant claim 9, however as shown above these compounds have been used individually for the same treatment therefore one of ordinary skill in the art would be motivated to combine them and administer to patients with insulin resistance.

The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Section MPEP 2144.07

The instant situation is amenable to the type of analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims, given the teaching of the prior art methods of using neostigmine and troglitazone individually for treating insulin resistance, it would have been obvious to use both compounds for the treatment of insulin resistance because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as therapeutic agents.

As to claims 14-15 are further rejected *With regard to kit claims*

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiele et al., Thiele et al., (1957) "Decrease in urinary sugar in diabetes mellitus by vagotonic treatment with neoeserine", *Munch Med Wochenschr.,* Aug 23;99(34): 1203-1206 (Applicants IDS) in view of American Diabetes Association 1998 as evident by drugdelivery.ca and http://syndromex.stanford.edu/InsulinResistance.htm as applied to claims 2, 5, 9-10, 12, 14-15, 17-19, 21, 25-29, 31-32, 43-45 above, and further in view of Dow US 6,194,454.

Dow teaches the combination of active ingredients in a kit, wherein the kit comprises a container and a direction for administration of the active agents. See col. 21, lines 60- col. 22lines 1-5.

The printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container.

See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, its is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of Patentability is concerned . . . In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must

also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively as well as *In re Ngai*, 70 USPQ2d 1862 (CAFC 2004). In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles or kits. The claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference

between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-3, 5-6, 8-10, 12-15, 17-19, 21-33, 36 and 43-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1 –7,9, 11, 15 24, 32-46** of U.S. Patent Application No. **11/597,032**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

The scope of the claims are the same, drawn to a method of reducing insulin resistance in a mammalian patient, administering a suitable acetylcholine esterase antagonist. The claims are directed to the same invention as that of claims in the co-pending of commonly assigned application **11/597,032.**

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 2-3, 5-6, 8-10, 12-15, 17-19, 21-33, 36 and 43-45 and copending application claims **1 –7,9, 11, 15 24, 32-46**. The compositions recited in the claims are obvious variation of each other.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H Marschel 10/15/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

SVG
10/9/07